



ATTORNEY'S DOCKET NUMBER: 2004367-0031

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Winterbottom *et al.* Examiner: Davis, Ruth A.  
Serial No: 10/735,135 Art Unit: 1651  
Filing Date: December 12, 2003  
Title: Formable and Settable Polymer Bone Composite and Method of  
Production Thereof

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**TRANSMITTAL LETTER**

Enclosed are the following documents:

1. Statement under 37 C.F.R. §§ 1.56, 1.97, and 1.98 (6 pages);
2. Form PTO-1449 (1 page);
3. Credit Card Payment Form; and
4. Return Postcard.

Respectfully submitted,

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Dated: December 28, 2006

**Certificate of Mailing**

I certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

December 28, 2006

Date

Signature

Nicole A. Dozier

Typed or Printed Name of person signing certificate



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Examiner: Davis, Ruth A.  
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Alexandria, VA 22313-1450

Sir:

**STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R §§ 1.56, 1.97 and 1.98, Applicant  
requests consideration of this Information Disclosure Statement.

**Type of Statement**

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or  
☒ A *supplemental* Information Disclosure Statement.

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Nicole A. Dozier

Name of Person Signing

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☐ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
  - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☐ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☒ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby certifies that *either*:
  - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
  - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making

reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or

☒ Includes herewith the fee set forth in § 1.17(p),

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

☐ Includes herewith the fee set forth in § 1.17(p).

## Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included, except for U.S. patents and published U.S. patent applications for which the submission requirements has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☒ A copy of each of the references cited on the attached form PTO-1449 (modified) is enclosed, except for U.S. patents and published U.S. patent applications for which the submission requirement has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☒ Does not contain non-English language citations;
- ☐ Includes one or more translations of a non-English citation; or
- ☐ Does contain non-English language citations, of which the following is a concise explanation:

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC § 102.

It is respectfully requested that:


1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and

3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated: December 28, 2006

  
C. Hunter Baker, M.D., Ph.D.  
Registration No. 46,533

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Sheet	1	Of	1	Application Number	10/735,135
				Filing Date	December 12, 2003
				First Named Inventor	Winterbottom <i>et al.</i>
				Art Unit	1651
				Examiner Name	Davis, Ruth A.
				Attorney Docket Number	2004367-0031

**U.S. PATENT DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,552,454	September 3, 1996	Kretschmann, et al.	
		US-5,624,463	April 29, 1997	Stone, et al.	
		US-5,837,752	November 17, 1998	Shastri, et al.	
		US-6,183,498	February 6, 2001	Devore, et al.	
		US-6,294,187	September 25, 2001	Boyce, et al.	
		US-6,376,573	April 23, 2002	White, et al.	
		US-6,441,073	August 27, 2002	Tanaka, et al.	
		US-6,696,073	February 24, 2004	Boyce, et al.	
		US-6,933,328	August 23, 2005	Schacht	
		US-2003/0045942	March 6, 2003	Lai, et al.	
		US-2003/0114552	June 19, 2003	Schacht	
		US-2003/0236573	December 25, 2003	Evans, et al.	
		US-2003/0039676	February 27, 2003	Boyce, et al.	
		US-2003/0180344	September 25, 2003	Wise, et al.	
		US-2004/0024457	February 5, 2004	Boyce, et al.	
		US-2004/0034434	February 19, 2004	Evans, et al.	
		US-2004/0064193	April 1, 2004	Evans, et al.	
		US-2004/0138758	July 15, 2004	Evans, et al.	
		US-2004/0146543	July 29, 2004	Shimp, et al.	
		US-2005/0008620	January 13, 2005	Shimp, et al.	
		US-2005/0129726	June 16, 2005	Liebschner	
		US-2005/0281856	December 22, 2005	McGlohorn, et al.	
		US-2005/0238683	October 27, 2005	Adhikari, et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.